K062465

510(k) SUMMARY
for

SEP - 6 2006

Zyoptix XP Epi Separator System
Prepared 23 May, 2006

1. Submitter Information

Sponsor: Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609

Contact Person: Ned Luce
Director, Global Regulatory Affairs
Telephone No.: (585) 338-6368
Fax No.: (585) 338-0702

2. Device Name

Classification Name: Keratome
21 CFR 886.4370
HNO
Proprietary Name: Zyoptix XP Epi Separator System

3. Predicate Device

Zyoptix XP Microkeratome K040204

4. Description of Device

The Epi Separator System is designed exclusively for use with the Zyoptix XP Microkeratome. The Zyoptix XP Separator System, which consists of the Epi Head and single use Epi separator, are optional accessories for the Zyoptix XP microkeratome.

5. Indications for Use

The Zyoptix XP Epi Separator System is indicated for the partial or complete delamination of the corneal epithelium in preparation for subsequent surgical procedures on the denuded cornea.

6. **Description of Safety and substantial equivalence**

The Medical Device Risk Analysis was performed comparing the changes made to the Zyoptix XP Microkeratome. The analysis concluded there are no additional unacceptable known risks.

7. **Basis of Equivalence**

The Zyoptix XP Epi Separator System is substantially equivalent to the Zyoptix XP Microkeratome cleared under 510(k) K040204 on March 22, 2004. A substantial equivalence Summary Table follows.

8. **Safety and Effectiveness**

Safety:
The Risk analysis applies to the changes made from the existing Zyoptix XP Microkeratome to the Zyoptix XP Epi Separator System. The analysis concluded there are no unacceptable risks known. A copy of the Risk Analysis is included in the appendix.

Effectiveness:
Design verification was conducted to demonstrate compliance to design requirements and specifications for the Zyoptix XP Epi Separator System. Sufficient objective evidence was collected to conclude that the design met the requirements outlined in the product requirements and technical specifications.

Substantial Equivalence Summary Table

SIMILARITIES

Characteristics	Zyoptix XP Microkeratome	Zyoptix XP Microkeratome with Zyoptix XP Epi Separator System
Operating Principal	Electrically driven oscillating blade housed in a head, which guides the blade across the cornea within controlled parameters.	Electrically driven oscillating blade housed in a head, which guides the blade across the cornea within controlled parameters.
Patient Contact Portion	• Suction Ring • Microkeratome Head • Blade	• Suction Ring • Microkeratome Head • Blade
Materials • Suction Ring • Microkeratome Head • Blade	 • Stainless Steel • Stainless Steel • Low Carbon Stainless Steel	 • Stainless Steel • Stainless Steel • Low Carbon Stainless Steel
Keratome Mechanism • Suction Ring • Electric motor • Control Mechanism • Cutting Principal	 • Single port annular suction fixation • DC powered 6 to 9 volts • Footswitch • Blade oscillation	 • Single port annular suction fixation • DC powered 6 to 9 volts • Footswitch • Blade oscillation
Sterilization	XP Blades EtO	Epi Separators EtO (same cycle as XP blades)
Cleaning, disinfection, sterilization by user	Instructions are in chapter 3 of the Operator's manual	Same instructions for the Epi

K062465

DIFFERENCES

Characteristics	**Zyoptix XP Microkeratome**	**Zyoptix XP Microkeratome with Zyoptix XP Epi Separator System**
Intended Use	Lamellear resection of the cornea preceding Lasik surgery or other treatment requiring initial lamellar resection of the cornea, where the flap is created in the Stromal layer	Partial or complete delamination of the corneal epithelium in preparation for subsequent surgical procedures on the denuded cornea .
Microkeratome head thickness plate	3 interchangeable heads with fixed thickness	1 interchangeable head designed to separate epithelium layer from Bowman's layer
Microkeratome blade	Blade edge designed to cut a flap in the Stromal layer	Blade edge designed to separate epithelium layer from Bowman's layer
Microkeratome head	Two piece design	One piece design

K062465

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

Bausch & Lomb, Inc.
1400 North Goodman St.
Rochester, NY 14609
Attn: Ned Luce

Re: K062465
Trade/Device Name: Zyoptix XP Epi Separator System
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome, AC-Powered
Regulatory Class: Class I
Product Code: HNO
Dated: August 24, 2006
Received: August 24, 2006

Dear Mr. Luce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number- K062465

Device Name: Zyoptix XP Epi Separator System

Indications for Use:

The Zyoptix XP Epi Separator System is indicated for the partial or complete delamination of the corneal epithelium in preparation for subsequent surgical procedures on the denuded cornea.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off)

Clay R. Buttemer

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number _____

510(K) Number K062465